



Wear simulation of total hip prostheses with polyethylene against CoCr, alumina and diamond-like carbon

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Abstract

The wear of ultra-high molecular weight polyethylene acetabular cups was studied with a new biaxial hip wear simulator using diluted calf serum as a lubricant. The cups had been packed and gamma-irradiated in argon. The cups were articulated against two established types of femoral head, alumina and CoCr, and one experimental type, CoCr coated with diamond-like carbon (DLC). The diameter of the heads was 28 mm. Polyethylene against alumina and against CoCr were studied because their clinical wear behaviour is relatively well known. The new simulator was validated with these established materials. The wear mechanisms, including the size and shape of the wear particles, agreed well with those seen in clinical studies. The average wear rates of the cups against alumina and CoCr heads were 48 and 56 mg per 1 million cycles, respectively. The order is in agreement with clinical observations. The average wear rate against DLC was 58 mg per 1 million cycles. As a counterface for polyethylene, DLC did not markedly differ from alumina and CoCr. © 2001 Elsevier Science Ltd. All rights reserved.

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1. Introduction

The severe wear problem posed by ultra-high molecular weight polyethylene (UHMWPE) acetabular cups of total hip prostheses has aroused considerable research activity in the field of biotribology. Wear particle accumulation in the tissues often leads to osteolysis and loosening of the prosthesis fixation, necessitating reoperation. The prevalence of osteolysis and loosening increases with increasing wear [1]. Various new materials, and modifications of established ones, have been suggested with a view to alleviating the problem. It has proved to be very difficult to predict the *in vivo* wear behaviour of materials, since not all clinical factors can be included in a laboratory wear simulation, which is always a simplification. Multidirectional motion and protein-containing lubricant appear to be factors which must be included [2–5].

The basic idea in the present study was to first compare the wear of polyethylene against alumina with that

against CoCr using a new, extremely simple hip wear simulator. The simulator was a simplified modification of the established biaxial rocking motion (BRM) simulator [2,3,6], which is the most commonly used hip wear simulator around the world. *In vivo*, the wear of polyethylene against alumina is usually lower than that against CoCr [7]. A wear simulator must not only reproduce this order, but also produce wear rates and wear mechanisms similar to those occurring *in vivo*. Results obtained for new material combinations have credibility only after the validation has been accomplished. The validation was followed by a test with polyethylene against diamond-like carbon (DLC) coating. The wear behaviour of this experimental material combination was compared with those of the above, established combinations. It has been proposed that DLC would be suitable for prosthetic joints, because it is hard and inert.

2. Materials and methods

The wear tests were done with a new three-station BRM hip wear simulator [5] (Fig. 1). The cup was located horizontally above the head. The cup was

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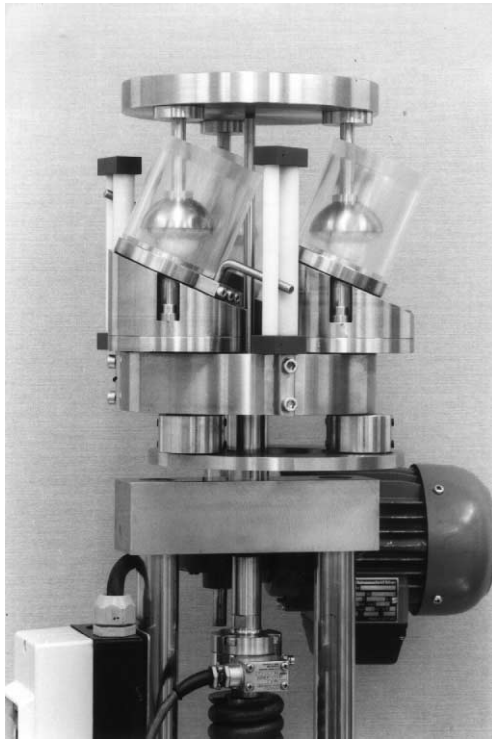


Fig. 1. Three-station, statically loaded biaxial rocking motion (BRM) hip wear simulator, designed and built by Dr. Saikko at Helsinki University of Technology. Note load-equalizing plate on top.

stationary, and the direction of the vertical, static 1 kN load was fixed relative to it. The head made biaxial, sinusoidal rocking motion at 1 Hz frequency. The phase difference between the two motions, both of 46° excursion, was $\pi/2$. For the theoretical point of load application, the integral $\int L(x) dx$, where L is load and x relative motion between specimens, was 34.4 N m per cycle with 28 mm head diameter.

The acetabular cups, catalogue number 1057-52, were supplied by Industrias Quirúrgicas de Levante s.a., Spain. They were actually metal-backed UHMWPE liners, similar to those used in earlier tests [5]. The material was Perplas IMP 2000, made from Hostalen GUR 1050 powder. The cups were machined from a compression-molded block. Twelve cups were used in the tests: nine test cups and three soak control cups. They were all from the same manufacture lot, and had been packed, gamma-irradiated (2.5–4 Mrad), and stored in argon, the average storage time before the tests being 11 months. The thickness of the polyethylene in the direction of load was 12 mm. The snap-lock lip on the outer surface was removed so that the cups could be taken from their titanium-alloy shells easily and without damage for periodic wear measurements based on a gravimetric method.

The femoral heads had a diameter of 28 mm. The average diametral clearance between the heads and the cups was 0.1 mm. Three different heads were studied:

alumina, CoCr and DLC-coated CoCr. All heads had similar surface roughness. The R_a value, the arithmetical mean surface roughness, was 0.010 ± 0.002 (SD) μm , measured with a Mahr Perthometer diamond stylus instrument, using 0.08 mm cutoff. The alumina heads were of Biolox Forte type, supplied by CeramTec AG, Germany. The other heads were supplied by Industrias Quirúrgicas de Levante s.a. The catalogue number of the CoCr heads was 1009-10. The heads which received the coating were of this same type. The coating was made by INASMET, Spain, using a proprietary, hybrid physical/chemical vapour deposition process, especially developed for biomedical applications. The coating thickness was 3 μm . Three simultaneous, identical tests were run first with alumina heads, then with CoCr heads, and lastly with DLC-coated heads, always against the same type of polyethylene cup. The head material was the only intentional variable in the tests.

The lubricant was prepared so that triple 0.1 μm sterile filtered, low-protein, low-endotoxin HyClone Alpha Calf Fraction serum, catalogue number SH30076.03, was diluted 1:1 with Millipore distilled water. Hence, the protein content of the lubricant was 21 mg/ml, close to that of synovial fluid. No additives were used in the lubricant. The volume of the lubricant, in which each joint was immersed during the tests, within acrylic receptacles, was 100 ml. When the cups were laid on the heads, care was taken that no air was left within the cups. An automatic water replenishment system based on surface tension compensated for the evaporation, preventing volume and concentration changes of the lubricant during the tests. A plastic cover was placed on the top of the simulator to reduce the risk of contaminants falling into the lubricant. The lubricant was changed twice a week, at each wear measurement stop.

The amount of wear was evaluated by stopping the test and weighing the cups at $300\,000 \pm 20\,000$ (SD) cycle intervals. The amount of fluid absorption was corrected by the use of soak control cups, one control cup per test, immersed in lubricant similar to that used with the test cups. During a weighing stop, the specimens and all components that had been in contact with the lubricant were carefully cleaned. Before the weighing, the cups were vacuum desiccated for 30 min. The weighing was done with a Mettler balance that had a resolution of 0.01 mg. After the weighing, the specimens were reassembled, and the test was continued with fresh lubricant. The total length of each test was 3 million cycles. Hence, there were 10 wear measurement points per test. The wear rate, expressed in mg per 1 million cycles, was taken to be the slope of the regression line in the diagram showing the variation of gravimetric wear with the number of cycles. As the density of the present polyethylene was 0.93 mg/mm^3 , and the value of the integral $\int L(x) dx$ was 34.4 N m, the wear factor k was calculated so that the wear rate was divided by $10^6 \times 0.93 \text{ mg/mm}^3 \times 34.4 \text{ N m}$.

The assessment of linear wear, that is, wear depth, of the cups, was based on the thickness change. The thickness was measured with a micrometer on the symmetry axis, which was the direction of wear, before the test, and a week after the completion of the test to allow for creep recovery. Moreover, as the load was only 1 kN, the proportion of creep in the measured thickness change was assumed to be negligible.

The temperature of the lubricant was not controlled, but it was periodically measured, because it reflected the amount of friction between the head and the cup. In the present simulator, friction could not be measured directly. The room temperature was $23 \pm 1^\circ\text{C}$.

After the tests, the bearing surface of the cups was examined, after sectioning and sputter-coating with a few nm of Au, by scanning electron microscopy (SEM) using a LEO 435 VP microscope and high-vacuum secondary electron signal.

Adapting a previously published method [9], polyethylene wear particles produced between 2 and 3 million cycles were isolated from the used serum. The 2 ml serum samples were first lyophilised, and then 10 ml of 5 N NaOH was added to the solid residuals. The digestion was done at 65°C for 6 h in closed Teflon vessels. After cooling, the neutralization was done with 1 N HCl. Using vacuum and methanol rinsing, the particles were filtered on $0.05 \mu\text{m}$ Nucleopore polycarbonate filters. The filtrate was identified by Fourier transform infrared spectroscopy (FTIR) and examined by SEM. FTIR spectra were collected using a Bio-Rad FTS6000 spectrometer equipped with a MTEC300 photoacoustic cell. Before the analysis, the cell was purged with helium for 5 min. The spectral data were taken with a resolution of 8 cm^{-1} and 200 scans co-added. For the SEM, pieces of the filters were fastened on sample holders with two-sided carbon tape and sputter-coated with about 5 nm of Au. The secondary electron images were obtained using a JEOL T 100 SEM, 15 keV beam energy, and 40 mm working distance. Representative micrographs were selected for image analysis. The particles were manually outlined and filled, and the images were converted to binary form by thresholding using an image processing program. The areas and equivalent circle diameters were obtained using an image analysis program. At least 130 particles were analyzed from each sample.

3. Results

The variation of gravimetric wear with number of cycles, together with the regression lines, is shown in Fig. 2. The wear rates, wear factors and lubricant temperatures are summarised in Table 1. The average gravimetric wear rate of polyethylene cups against alumina heads was lower than that against CoCr heads ($P = 0.20$). The

average gravimetric wear rate of polyethylene cups against DLC-coated heads was higher than that produced by alumina ($P = 0.06$) and by CoCr ($P = 0.44$) heads. The total weight gains of the soak control cups, 0.5–2.2 mg, were small compared with the total weight losses of the test cups, which were 130–213 mg. Fig. 3 illustrates the correlation between total gravimetric wear and total linear wear.

After articulation against femoral heads, the bearing surface of all test cups looked polished in visual examination. There were no signs of wear on the outer surface of the cups. SEM on the bearing surface of the cups revealed, as a typical feature, a fringe-like appearance in the micrometer range (Fig. 4a–c). The majority of the polyethylene wear particles detected on the filters were in the $0.1\text{--}1 \mu\text{m}$ size range, the equivalent circle diameters being 0.26 ± 0.12 , 0.35 ± 0.17 and $0.32 \pm 0.15 \mu\text{m}$ in tests 1, 2 and 3, respectively (Figs. 5 and 6). By FTIR, the filtrate was identified as polyethylene. For FTIR, it was necessary to digest larger serum samples to have abundantly polyethylene on the filter.

After the tests, all heads proved to be practically unchanged in visual and microscopical examination. The alumina heads showed slight texturing, but the surface roughness value R_a was unchanged, as was the R_a value of the CoCr and DLC heads.

4. Discussion

The visual and microscopical appearance of the bearing surface of the polyethylene cups (Fig. 4), and the microscopical appearance and size of the polyethylene wear particles (Figs. 5 and 6) agreed well with clinical findings [2,8–12]. In total hip prostheses, the adhesive wear mechanism is known to be responsible for the unfortunate production of an enormous number of microscopic polyethylene wear particles. The majority of polyethylene particles isolated from periprosthetic tissues are in the size range of $0.1\text{--}1 \mu\text{m}$ [2,9–12]. The fringe-like appearance of the bearing surface is typical of the adhesive wear mechanism. Fig. 4d is a scanning electron micrograph from the high wear area of a retrieved polyethylene cup, showing fringes similar to those produced in the present wear tests. The retrieved prosthesis was a Lubinus with CoCr head, and it had been in vivo for 97 months.

In one clinical study, the average wear rate of polyethylene cups against alumina heads was 50 per cent lower than that against CoCr heads [7]. On the other hand, another clinical study showed no difference between metal and ceramic head groups [13]. In the present simulator tests, the difference in the average gravimetric wear rate was 14 per cent. In vivo, metallic heads are often scratched by various abrasive particles, which has been shown to increase the wear of

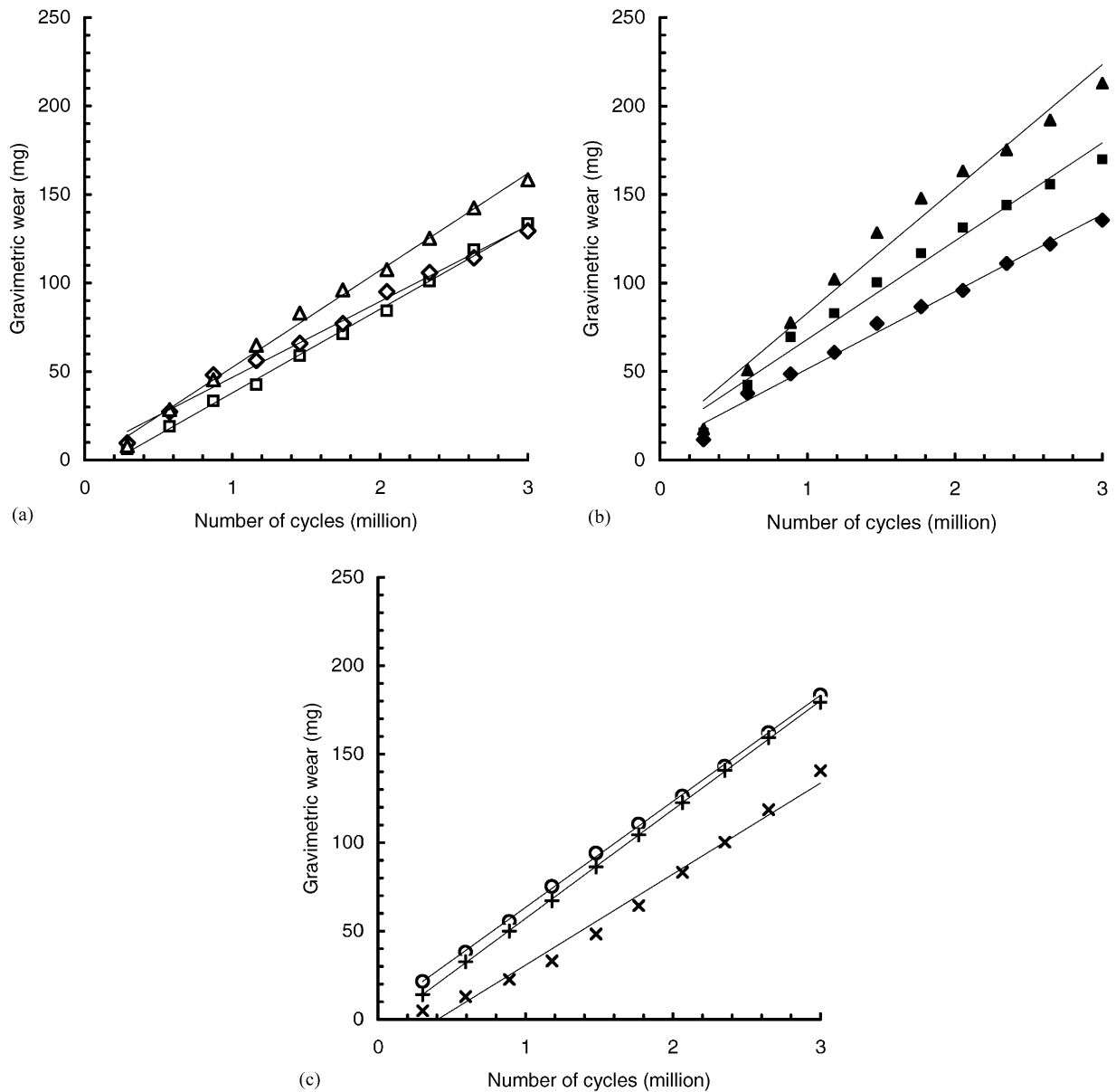


Fig. 2. Variation of gravimetric wear of polyethylene acetabular cups with number of cycles against (a) alumina heads, (b) CoCr heads, and (c) DLC-coated heads.

Table 1

Summary of wear of polyethylene acetabular cups, and of lubricant temperatures. Individual values, average values, and standard deviations

Test no.	Head material	Station no.	Wear rate (mg/10 ⁶ cycles)		Wear factor (10 ⁻⁶ mm ³ /N m)		Lubricant temperature (°C)	
1	Alumina	1	47.3	48.3 ± 6.0	1.48	1.51 ± 0.19	32.7	33.3 ± 0.7
		2	42.9		1.34		34.0	
		3	54.8		1.71		33.1	
2	CoCr	1	55.5	56.4 ± 13.3	1.73	1.76 ± 0.42	36.4	36.3 ± 0.1
		2	43.6		1.36		36.3	
		3	70.2		2.19		36.2	
3	DLC	1	51.5	57.7 ± 5.5	1.61	1.80 ± 0.17	35.2	34.4 ± 0.8
		2	60.0		1.88		34.4	
		3	61.6		1.93		33.6	

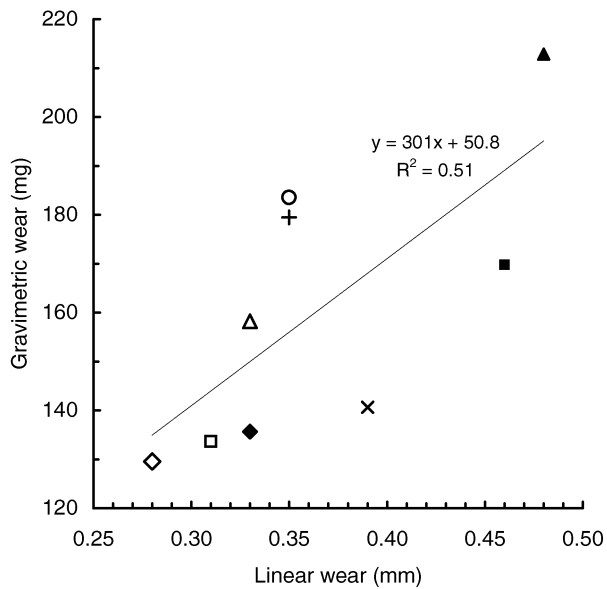


Fig. 3. Correlation between total gravimetric wear and total linear wear of polyethylene acetabular cups.

polyethylene cups [14]. The presence of bone cement particles in the wear test has been found to dramatically increase the wear rate of polyethylene cups articulating against CoCr heads [15]. Alumina has a superior resistance to abrasion, which may be the reason why most clinical studies show a lower average polyethylene wear rate in the ceramic head group compared with the metal head group. The average linear wear rates of polyethylene cups against alumina and CoCr heads in the radiographic study were 0.1 and 0.2 mm per year, respectively [7]. The corresponding values in the present study were 0.1 and 0.14 mm per 1 million cycles. One million cycles in a simulator is generally taken to represent 1 year in vivo. Hence, the linear wear rate against alumina was equal to that in [7], but the linear wear rate against CoCr was lower, possibly because none of the heads were damaged in the present test. In all comparisons, however, it must be borne in mind that polyethylenes show considerable variation in wear resistance, depending on the method of manufacture and sterilization [3]. Many clinical wear studies do not specify the type of polyethylene, which makes them problematic for use as references in wear simulation studies.

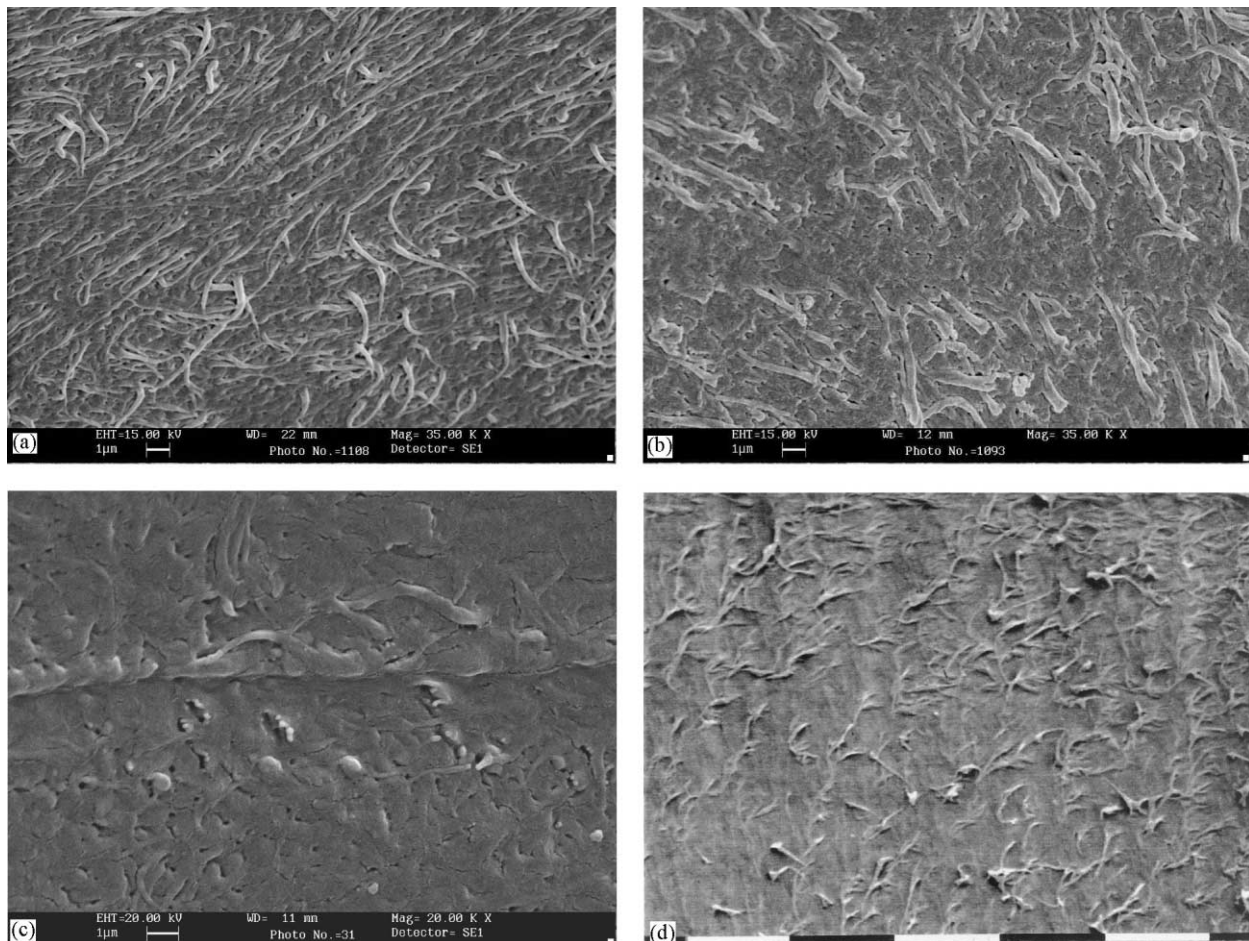


Fig. 4. Scanning electron micrograph of bearing surface of polyethylene acetabular cup worn in hip wear simulator for 3 million cycles against (a) alumina head, (b) CoCr head, (c) DLC-coated head, and (d) in vivo for 97 months against CoCr head. In (d), one section in the scalebar corresponds to 10 μ m.

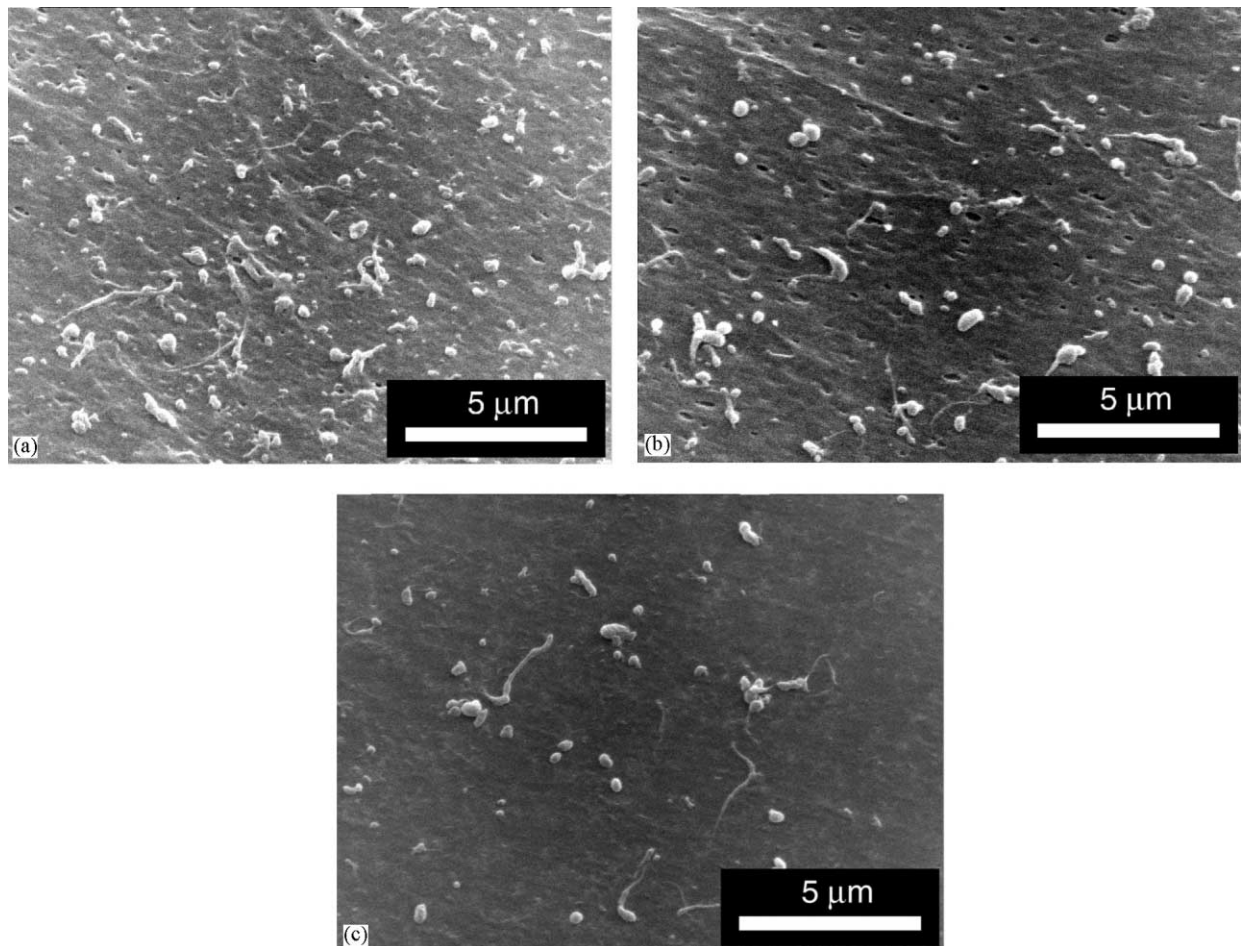


Fig. 5. Scanning electron micrograph of polyethylene wear particles produced in hip wear simulator against (a) alumina head, (b) CoCr head, and (c) DLC-coated head.

The average gravimetric wear rate of polyethylene cups against CoCr heads in the present study, 56 mg per 1 million cycles, is nevertheless in reasonable agreement with clinical observations. The *in vivo* wear rate is usually in the range of 50–100 mg per year [14,16–18]. In many earlier simulator studies [4–6,19,20], the polyethylene wear rate was lower, viz. 20–35 mg per 1 million cycles. It has been suggested that the type of serum plays an important role [21]. The HyClone Alpha Calf Fraction serum was used because it was earlier used successfully in the MTS version of the BRM simulator [3], which differs from the present one only with respect to its dynamic load and larger lubricant receptacle. With 32 mm CoCr heads, the MTS-BRM simulator produced a wear rate of 40 mg per 1 million cycles for irradiated GUR 415 cups [3].

In the authors' earlier BRM simulator study using the single-station prototype [5], the wear rates of similar cups were 22 and 23 mg per 1 million cycles against alumina and CoCr, respectively. In that study, Sigma B-2771 adult bovine serum was used as the lubricant,

diluted 1:2 with distilled water, resulting in a protein concentration of 24 mg/ml. Sodium azide was added to the lubricant (0.2 per cent), and the lubricant change interval was as long as 1 million cycles. The differences in the lubrication conditions may explain the large differences in wear between these two studies. The present tests did not show any need for the use of sodium azide or EDTA.

As a counterface for polyethylene, the experimental DLC coating appears to be fairly similar to alumina and CoCr. The reliability of the finding is supported by the fact that the simulator produced valid results for alumina and CoCr, which are well-established materials. Although DLC produced the highest average polyethylene wear rate, the differences between the three head materials were not large.

The average R^2 value of the linear regression for the gravimetric wear of all tests (Fig. 2) was 0.9904. The high value indicated that 3 million cycles was a sufficient test length, as the wear rates remained fairly constant throughout the tests. It indicated also that the simulator,

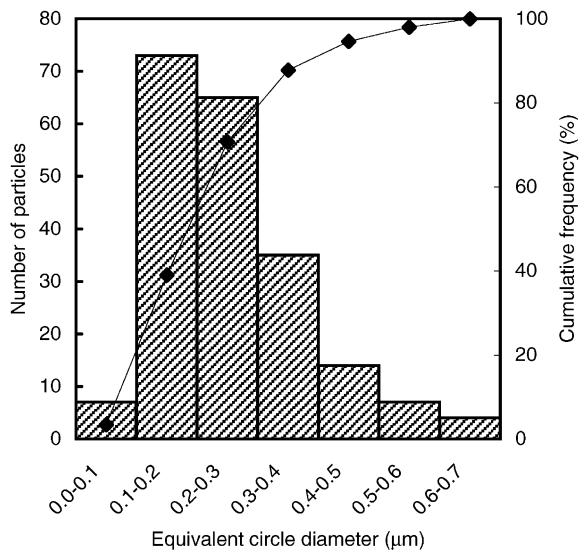


Fig. 6. Size distribution of polyethylene wear particles produced in hip wear simulator against alumina head.

the test method, and the method of wear measurement were sound. The R^2 value of 0.9999 in station 3 of test 3 is certainly remarkable. The lowest value, in station 3 of test 2, was 0.9784. The relatively high variance in the wear rate between the test stations in test 2 was odd, however, because three tests as similar as possible were done with each of the three material combinations (Table 1). No obvious reason for the variance appeared. Still test 2 showed minimal variance in lubricant temperatures. It would be erroneous to simply claim that the test stations of the simulator were not similar. Although in all three tests, the highest wear rate was produced in station 3, and in tests 1 and 2, the lowest wear rate in station 2, still in test 3, the wear rate produced in station 2 was very close to that produced in station 3.

The average lubricant temperatures, 33°C with alumina heads and 36°C with CoCr heads (Table 1), were consistent with another BRM simulator study [22]. With this original MMED version of the BRM simulator, friction was measured in HyClone bovine serum lubricant, and it was found that the friction of polyethylene against alumina was roughly 25 per cent lower than that of polyethylene against CoCr [19]. Similar results were achieved also in [23]. However, it should be noted that the differences in the lubricant temperature reflect not only differences in friction, but also differences in the thermal conductivity of the head materials. A general observation on the present tests was that there is no need for temperature control, if the frictional heat does not raise the lubricant temperature above 40°C. There are two simple ways to avoid overheating. First, the lubricant volume should be high enough. Second, the lubricant receptacle should be open so that there is effective convection of heat from the lubricant to the atmosphere through evaporation.

The main difference between the present BRM simulator and the previous types [2,3,6] is the load, static vs. dynamic. All earlier BRM simulators have employed various dynamic load waveforms. There were two principal reasons for using static load in the present study. First, the analogous circularly translating pin-on-disk (CTPOD) device produced realistic wear with static load [24]. Second, since the force locus in the BRM simulator is circular (because the abduction–adduction has an exaggerated excursion, equal to that of the flexion–extension), instead of an elongated loop as suggested by a biomechanical analysis [25], and since the wear simulation has nevertheless proved to be realistic [2,3,6], it was assumed that the load need not be an exact reproduction of the true situation, either. When the load is static, it is possible to build a very simple and reliable test device, which is easy to operate and which needs minimal service. The present study showed that static load is sufficient, because the validity of the results is not compromised. The value 1 kN is the average value of a typical load waveform [26]. Moreover, two-axis motion is clearly adequate. Internal–external rotation as a third motion would only increase, unnecessarily, the complexity of the simulator, without really improving the validity of the results. The internal–external rotation is in fact redundant with respect to the crucial factor, multidirectional motion, in other words, the continual change of the direction of sliding.

5. Conclusions

The widely used biaxial rocking motion (BRM) principle of hip wear simulation was shown to produce valid results even with static 1 kN load. In the validation of a new, substantially simplified version of the BRM simulator, the wear of polyethylene against alumina was compared with that against CoCr using diluted calf serum as a lubricant. The wear behaviour of these established material combinations, including the size and shape of the wear particles, agreed well with clinical studies. As a counterface for polyethylene, the experimental DLC coating did not markedly differ from alumina and CoCr.

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